

REMARKS/ARGUMENTS

The Office Action mailed June 28, 2004 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested. The claims presented for examination are: claims 1, and 3-9.

35 USC 112 Rejection

In numbered paragraphs 4 and 5 of the Office Action mailed June 28, 2004, claims 1 and 3-9 were rejected under 35 USC 112 as being indefinite. Specifically, claim 1 was rejected as vague and indefinite because applicant has not recited from what reference point the change is measured.

Independent claim 1 has been amend to specify a reference point for the change that is measured by adding the following phrase identified by the underlining: "measuring the impedance between the spaced electrodes prior to said sample fluid containing pathogens and the antibody coated beads being directed past the spaced electrodes."

Support for the additional phrase is found in applicants' specification. For example the following portion of applicants' specification supports the phrase:

"An impedance measurement between electrodes 20 and 18 is made prior to the passage of the sample fluid across the electrodes and after passage of the sample fluid, and the change in the impedance caused by the trapped pathogen is determined and measured to detect the presence of the pathogen by the impedance sensor of Figure 7. To amplify the impedance change signal, one or more beads 25 coated with antibodies can be introduced to the signal area (electrodes 20-18) as shown in Figure 5." (Page 8, lines 5-12)

Applicants believe that amended independent claim 1 and dependent claims 3-9 comply with the requirements of 35 USC 112.

### 35 USC 103(a) Rejection – Setter in view of Pyle

In numbered paragraph 9 of the Office Action mailed June 28, 2004, claim 8 was rejected under 35 USC 103(a) as allegedly being unpatentable over the primary Setter et al reference (U.S. Pat. 5,567,301) in view of the secondary Pyle et al reference (U.S. Pat. 5,821,066).

The primary Setter et al reference is directed to, “a biosensor comprising a substrate material, at least one antibody covalently immobilized on the substrate material, and a pair of metal contact electrodes for measuring the impedance of the biosensor.” (Abstract, Setter et al Reference)

The secondary Pyle et al reference is directed to, “method includes steps of a) passing a microbial sample through a collecting device to capture the cells; b) adding to the collecting device a fluorochrome dye specific for the detection of respiring cells and allowing the dye to incubate; c) treating the collecting device with a reactive fluorescent antibody which reacts with a target microorganism of interest present in said microbial sample; d) mounting the collecting device for examination by fluorescence microscopy in which a suitable light system is used to excite the fluorochrome dye and fluorescent antibody to fluoresce; and e) quantifying the respiring cells.” (Abstract, Pyle et al Reference)

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include “Ascertaining the differences between the prior art and the claims at issue.”

The differences between the primary Setter et al reference and Applicants’ invention defined by amended claim 1 includes the fact that the primary Setter et al reference does not show the following steps of applicants’ amended claim 1:

“providing antibody coated beads,” or

“directing a sample fluid containing pathogens and the antibody coated beads past the spaced electrodes,” or

“allowing the antibody coated beads to stick to the pathogens that are bound to the antibodies that are deposited on the spaced electrodes,” or

“measuring the impedance between the spaced electrodes prior to said sample fluid containing pathogens and the antibody coated beads being directed past the spaced electrodes,” or

“determining the presence of pathogens attached to the antibodies by measuring change in impedance between said pair of spaced electrodes with the antibody coated beads amplifying the change in impedance.”

The Pyle et al reference discloses “magnetic beads” that are separated in a magnetic separator. The Pyle et al reference does not show the method of applicants’ amended claim 1.

There is no suggestion or motivation to combine the primary Setter et al reference and the secondary Pyle et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the primary Setter et al and the secondary Pyle et al references to produce Applicant’s invention, a 35 U.S.C §103(a) rejection of Applicant’s amended independent claim 1 would not be appropriate. Applicants respectfully submit that independent claim 1 is patentable and since the other claims depend from independent claim 1, all the claims presented for examination, claims 1, and 3-9 are patentable.

35 USC 103(a) Rejection – Clerc in view of Pyle et al

In numbered paragraph 10 of the Office Action mailed June 28, 2004, claims 1, 4, and 7 were rejected under 35 USC 103(a) as allegedly being unpatentable over the primary Clerc reference (U.S. Patent No. 6,133,046) in view of the secondary Pyle et al reference.

The primary Clerc reference is directed to, "An apparatus for detecting an analyte in a sample, including a cell with at least one fixed electrode, at least one mobile electrode opposite the fixed electrode, the mobile electrode being configured to move with respect to the fixed electrode, and a sample receiving cavity defined by a space between the fixed electrode and the mobile electrode, wherein a surface of at least one of the fixed electrode and mobile electrode facing the sample receiving cavity is configured to bound a ligand of the analyte to be detected." (Abstract, Clerc Reference)

The secondary Pyle et al reference is directed to, "method includes steps of a) passing a microbial sample through a collecting device to capture the cells; b) adding to the collecting device a fluorochrome dye specific for the detection of respiring cells and allowing the dye to incubate; c) treating the collecting device with a reactive fluorescent antibody which reacts with a target microorganism of interest present in said microbial sample; d) mounting the collecting device for examination by fluorescence microscopy in which a suitable light system is used to excite the fluorochrome dye and fluorescent antibody to fluoresce; and e) quantifying the respiring cells." (Abstract, Pyle et al Reference)

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Clerc reference and Applicants' invention defined by amended claim 1 includes the fact that the primary Clerc reference does not show the following steps of applicants' amended claim 1:

"providing antibody coated beads," or

"directing a sample fluid containing pathogens and the antibody coated beads past the spaced electrodes," or

"allowing the antibody coated beads to stick to the pathogens that are bound to the antibodies that are deposited on the spaced electrodes," or

"measuring the impedance between the spaced electrodes prior to said sample fluid containing pathogens and the antibody coated beads being directed past the spaced electrodes," or

"determining the presence of pathogens attached to the antibodies by measuring change in impedance between said pair of spaced electrodes with the antibody coated beads amplifying the change in impedance."

The Pyle et al reference discloses "magnetic beads" that are separated in a magnetic separator. The Pyle et al reference does not show the method of applicants' amended claim 1.

There is no suggestion or motivation to combine the primary Clerc reference and the secondary Pyle et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the primary Clerc and the secondary Pyle et al references to produce Applicant's invention, a 35 U.S.C.

§103(a) rejection of Applicant's amended independent claim 1 would not be appropriate. Applicants respectfully submit that independent claim 1 is patentable and since the other claims depend from independent claim 1, all the claims presented for examination, claims 1, and 3-9 are patentable.

35 USC 103(a) Rejection - Vadgama et al in view of Pyle et al

In numbered paragraph 10 of the Office Action mailed June 28, 2004, claims 1, 3-7, and 9 were rejected under 35 USC 103(a) as allegedly being unpatentable over Vadgama et al (WO 98/19153) in view of Pyle et al (U.S. Pat. 5,821,066).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Vadgama et al reference and Applicants' invention defined by amended claim 1 includes the fact that the following steps of amended claim 1 are not found in the primary Vadgama et al reference:

"providing antibody coated beads," or

"directing a sample fluid containing pathogens and the antibody coated beads past the spaced electrodes," or

"allowing the antibody coated beads to stick to the pathogens that are bound to the antibodies that are deposited on the spaced electrodes," or

"measuring the impedance between the spaced electrodes prior to said sample fluid containing pathogens and the antibody coated beads being directed past the spaced electrodes," or

“determining the presence of pathogens attached to the antibodies by measuring change in impedance between said pair of spaced electrodes with the antibody coated beads amplifying the change in impedance.”

The Pyle et al reference discloses “magnetic beads” that are separated in a magnetic separator. The Pyle et al reference does not show the method of applicants’ amended claim 1.

There is no suggestion or motivation to combine the primary Vadgama et al reference and the secondary Pyle et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the primary Vadgama et al and the secondary Pyle et al references to produce Applicant’s invention, a 35 U.S.C. §103(a) rejection of Applicant’s amended independent claim 1 would not be appropriate. Applicants respectfully submit that independent claim 1 is patentable and since the other claims depend from independent claim 1, all the claims presented for examination, claims 1, and 3-9 are patentable.

35 USC 103(a) Rejection – Van Gerwen et al in view of Pyle et al

In numbered paragraph 12 of the Office Action mailed June 28, 2004, claims 1, 3-7, and 9 were rejected under 35 USC 103(a) as allegedly being unpatentable over Van Gerwen et al (WO 97/21094) in view of Pyle et al (U.S. Pat. 5,821,066).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include “Ascertaining the differences between the prior art and the claims at issue.”

The differences between the primary Van Gerwen et al reference and Applicants’ invention defined by amended claim 1 includes the fact that the following steps of amended claim 1 are not found in the primary Van Gerwen et al reference:

“providing antibody coated beads,” or

“directing a sample fluid containing pathogens and the antibody coated beads past the spaced electrodes,” or

“allowing the antibody coated beads to stick to the pathogens that are bound to the antibodies that are deposited on the spaced electrodes,” or

“measuring the impedance between the spaced electrodes prior to said sample fluid containing pathogens and the antibody coated beads being directed past the spaced electrodes,” or

“determining the presence of pathogens attached to the antibodies by measuring change in impedance between said pair of spaced electrodes with the antibody coated beads amplifying the change in impedance.”

The Pyle et al reference discloses “magnetic beads” that are separated in a magnetic separator. The Pyle et al reference does not show the method of applicants’ amended claim 1. Further, there is no suggestion or motivation to combine the primary Van Gerwen et al reference and the secondary Pyle et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed



combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the Van Gerwen et al and the Pyle et al references to produce Applicant's invention, a 35 U.S.C. §103(a) rejection of Applicant's amended independent claim 1 would not be appropriate. Applicants respectfully submit that independent claim 1 is patentable and since the other claims depend from independent claim 1, all the claims presented for examination, claims 1, and 3-7 and 9 are patentable.

35 USC 103 Rejection - Clark et al in view of Kipling et al and Pyle et al

In numbered paragraph 13 of the Office Action mailed June 28, 2004, claims 1, 3-4, 7, and 9 were rejected under 35 USC 103(a) as allegedly being unpatentable over Clark et al (U.S. Pat. 5,194,133) in view of Kipling et al (U.S. Pat. 5,374,521) and Pyle et al (U.S. Pat. 5,821,066).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Clark et al reference and Applicants' invention defined by amended claim 1 includes the fact that the following elements of amended claim 1 is not found in the primary Clark et al reference:

"providing antibody coated beads," or

"directing a sample fluid containing pathogens and the antibody coated beads past the spaced electrodes," or

"allowing the antibody coated beads to stick to the pathogens that are bound to the antibodies that are deposited on the spaced electrodes," or

“measuring the impedance between the spaced electrodes prior to said sample fluid containing pathogens and the antibody coated beads being directed past the spaced electrodes,” or

“determining the presence of pathogens attached to the antibodies by measuring change in impedance between said pair of spaced electrodes with the antibody coated beads amplifying the change in impedance.”

While the Kipling et al and Pyle et al references disclose “beads,” the Kipling et al and Pyle et al references do not show the method of claim 1. Further, there is no suggestion or motivation to combine the primary Clark et al reference and the secondary Kipling et al reference and the tertiary Pyle et al reference. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the Clark et al and the Kipling et al and the Pyle et al references to produce Applicant’s invention, a 35 USC §103(a) rejection of Applicant’s amended independent claim 1 would not be appropriate. Applicants respectfully submit that independent claim 1 is patentable and since the other claims depend from independent claim 1, all the claims presented for examination including claims 1, and 3-4, 7, and 9 are patentable.

35 USC 103 Rejection - Clark et al, Kipling et al, Pyle et al, and Taylor et al

In numbered paragraph 14 of the Office Action mailed June 28, 2004, claims 5, 6, and 8 were rejected under 35 USC 103(a) as allegedly being unpatentable over Clark et al (U.S. Pat. 5,194,133) in view of Kipling et al (U.S.

Pat. 5,374,521) and Pyle et al (U.S. Pat. 5,821,066) further in view of Taylor et al (U.S. Pat. 5,001,048).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Clark et al reference and Applicants' invention defined by amended claim 1 includes the fact that the following elements of amended claim 1 are not found in the primary Clark et al reference:

"providing antibody coated beads," or

"directing a sample fluid containing pathogens and the antibody coated beads past the spaced electrodes," or

"allowing the antibody coated beads to stick to the pathogens that are bound to the antibodies that are deposited on the spaced electrodes," or

"measuring the impedance between the spaced electrodes prior to said sample fluid containing pathogens and the antibody coated beads being directed past the spaced electrodes," or

"determining the presence of pathogens attached to the antibodies by measuring change in impedance between said pair of spaced electrodes with the antibody coated beads amplifying the change in impedance."

While the Kipling et al and Pyle et al references disclose "beads," the Kipling et al and Pyle et al references do not show the method of Applicants' amended claim 1. The Taylor et al reference does not show beads. Further, there is no suggestion or motivation to combine the Clark et al and the Kipling et al and the Pyle et al and the Taylor et al references. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the

references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the Clark et al and the Kipling et al and the Pyle et al and the Taylor et al references to produce Applicant's invention, a 35 U.S.C. §103(a) rejection of Applicant's amended independent claim 1 would not be appropriate. Applicants respectfully submit that independent claim 1 is patentable and since the other claims depend from independent claim 1, all the claims presented for examination including claims 1, and 3-4, 7, and 9 are patentable.

35 USC 103 Rejection – Van Gerwen, Vadgama, Setter, Clerc, Pyle, Taylor

In numbered paragraph 15 of the Office Action mailed June 28, 2004, claim 8 was rejected under 35 USC 103(a) as allegedly being unpatentable over Van Gerwen et al (WO 97/21094), Vadgama et al (WO 98/19153), Setter et al (U.S. Pat. 5,567,301), or Clerc (U.S. Pat. 6,133,046) in view of Pyle et al (U.S. Pat. 5,821,066) and Taylor et al (U.S. Pat. 5,001,048).

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 USC 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the primary Van Gerwen et al reference and Applicants' invention defined by amended claim 1 includes the fact that the following elements of amended claim 1 are not found in the primary Van Gerwen et al reference:

"providing antibody coated beads," or

“directing a sample fluid containing pathogens and the antibody coated beads past the spaced electrodes,” or

“allowing the antibody coated beads to stick to the pathogens that are bound to the antibodies that are deposited on the spaced electrodes,” or

“measuring the impedance between the spaced electrodes prior to said sample fluid containing pathogens and the antibody coated beads being directed past the spaced electrodes,” or

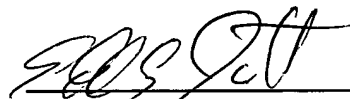
“determining the presence of pathogens attached to the antibodies by measuring change in impedance between said pair of spaced electrodes with the antibody coated beads amplifying the change in impedance.”

There is no suggestion or motivation to combine the Van Gerwen et al and the Vadgama et al, Setter et al, Clerc et al, Pyle et al, and Taylor et al references. Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. In re Vaack, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation to combine the references to produce Applicant’s invention, a 35 USC §103(a) rejection of Applicant’s amended independent claim 1 would not be appropriate. Applicants respectfully submit that independent claim 1 is patentable and since the other claims depend from independent claim 1, all the claims presented for examination including claims 1, and 3-4, 7, and 9 are patentable.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated June 28, 2004 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



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